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Attorney Docket No. 22918/1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:

Lucia Irene Gonzalez-Villasenor

Application No.:

10/080,919

Group Art Unit:

FILED:

February 22, 2002

Examiner:

FOR:

Methods and Composition for Production of Recombinant Peptides

CERTIFICATE OF MAILING BY FIRST CLASS MAIL (37 CFR 1.8)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner of Patents, Washington, D.C. 20231 on:

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Date

INFORMATION DISCLOSURE STATEMENT (SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE THE MAILING DATE OF A FIRST OFFICE ACTION ON THE MERITS)

Assistant Commissioner of Patents Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

Application No.: 10/080,919 Filed: February 22, 2002 Group Art Unit:

I. <u>LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION</u>

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II.	COPIES	
	a. <u>X</u>	Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
III.	CONCISE I	EXPLANATION OF THE RELEVANCE
	(che	ck at least one box)
	a. <u>X</u>	Except as may be indicated below in (b), all of the patents, publications
		or other information are in the English language or were cited in an
		English language Search Report, a copy of which is attached hereto
		(concise explanation not required).
	b	A concise explanation of the relevance of all patents, publications or othe
		information listed that is not in the English language is as follows:
	c	The following additional information is provided for the Examiner's

consideration:

Application No.: 10/080,919 Filed: February 22, 2002 Group Art Unit:

<u>FEES</u>

IV.	THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b)						
	(check one b	ox)					
	a	within three months of the filing date of a national application (37 C.F.R.					
		§ 1.97(b) (1)). No fee or certification is required.					
	b	within three months of the date of entry of the national stage as set forth in					
		§1.491 in an international application (37 C.F.R. § 1.97(b) (2)). No fee or					
		certification is required.					
	c. <u>X</u>	before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)					
		(3)). No fee or certification is required. In the event that a first Office					
		Action on the merits has been issued, please consider this IDS under 37					
		C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e)below,					
		or, if no certification has been made, charge our deposit account a fee in					
		the amount of \$240.00 as required by 37 C.F.R. § 1.17(p).					
V.	THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):						
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	before the m	ailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. §					
	1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311						
	(See 37 C.F.R. § 1.97(c) (2)).						
	a	No certification; therefore, a fee in the amount of \$240.00 is required by					
		37 C.F.R § 1.17(p).					
		or					
	b. <u>X</u>	See the certification below. No fee is required.					

Application No.: 10/080,919 Filed: February 22, 2002 Group Art Unit:

VI. <u>CERTIFICATION UNDER 37 C.F.R. § 1.97(e)</u> (check <u>only</u> one box)

The undersigned hereby certifies that

a	each item of information contained in the IDS was cited in a
	communication from a foreign Patent Office in a counterpart foreign
	application not more than three months prior to the filing of this IDS; or
b	no item of information contained in the IDS was cited in a communication
	from a foreign Patent Office in a counterpart foreign application or, to the
	best of my knowledge after making reasonable inquiry, was known to any
	individual designated in 37 C.F.R. § 1.56(c) more than three months prior
	to the filing of this statement.
c	Some of the items of information were cited in a communication from a
	foreign Patent Office. As to this information, the undersigned certifies
	that each item of information contained in the IDS was cited in a
	communication from a foreign Patent Office in a counterpart foreign
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	of this remaining information contained in the IDS was cited in a
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	inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c)
	more than three months prior to the filing of this statement.
	Please charge Deposit Account No. 500369 in the amount of \$180.00 for the
	above-indicated fee. A triplicate copy of this paper is attached.
	above-indicated icc. A tripheate copy of this paper is attached.
X	No fee is required.

Application No.: 10/080,919 Filed: February 22, 2002

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VII. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.704(d) (PATENT TERM **ADJUSTMENT**)

Applies to origin	nal applications (other than design) filed on or after May 29, 2000					
a	Each item of information contained in the Information Disclosure					
	Statement was cited in a communication from a foreign patent office in					
	a counterpart application and this communication was not received by					
	any individual designated in § 1.56(c) more than thirty days prior to the					
	filing of the Information Disclosure Statement.					
b. X Enclosed herewith is form PTO-1449.						
c. <u>X</u>	Copies of cited references are enclosed.					
d	The listed references were cited in the enclosed International Search.					
	Report in a counterpart foreign application.					
If the Exam	iner has any questions concerning this IDS, he/she is requested to contact the					
	s determined that this IDS has been filed under the wrong rule, the PTO is					
	er this IDS under the proper rule (with a petition, if necessary) and charge the					
•	Deposit Account No. 500369.					
	Respectfully submitted,					
Date:						
	Thomas M. Saunders, Esq.					
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ATTY DOCKET NO. SERIAL NO. **FORM PTO-1449** 10/080,919 INFORMATION DISCLOSURE STATEMENT 22918/1 APPLICANT(S): Lucia Irene Gonzalez-Villasenor FILING DATE: ART UNIT: February 22, 2002 UNITED STATES PATENT DOCUMENTS SUB FIL. EXAM. DOCUMENT **CLASS** DATE IF DATE CLASS INITIAL NUMBER INVENTOR APPR 06/04/1996 435 69.1 Cousens et. al. 5,523.215 06/30/1987 Rausch et. al. 530 412 4,677, 196 FOREIGN PATENT DOCUMENTS DOCUMENT NUMBER DATE **COUNTRY** CLASS SUB TRAN CLASS Y/N 14/495 Y Nov. 27 1990 **EPO** C07K EP 0 433 225 B1 OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) "Recombinant-DNA-derived bovine growth hormone from Escherichia coli", Keith E. Langley et. al., Eur J. Biochem, 163, pp 313-321, (1987) "Plasminogen activator inhibitor-1 fused with erythropoietin (EPO) mimetic peptide (EMP) enhances the EPO activity of EMP", Le-tian Kuai et.al., J. Peptide Res., 56, 2000, pp 59-62 "Biopharmaceutical formulation", J. Ching Lee, Current Opinion in Biotechnology, 2000, 11, pp 81-84 "Purification and Characterization of Human Interleukin-1 Expressed in Escherichia Coli", Shirley R. Kronheim et.al., Bio Technology, Vol. 4, December 1986, pp 1078-1082 "Expression, renaturation and purification of recombinant human interleukin 4 from Escherichia coli", Anita van Kimmenade et. al., Eur. J. Biochem, pp 109-114 (1988) "Expression of a biologically active fragment of human IgE ε chain in Escherichia coli, Fu-Tong Liu et. al., Proc. Natl. Acad. Sci. USA, Vol. 81, pp 5369-5373, September 1984 "Renaturation of Escherichia coli Tryptophanase after Exposure to 8 M Urea, Evidence for the Existence of Nucleation Centers", Jacqueline London et. al., Eur. J. Biochem. 47, 409-415 (1974) "Inclusion Bodies from Proteins Produced at High Levels in Escherichia coli", Joanna K. Krueger et. al., Amer. Assoc. for the Adv. Science, 1990, pp 136-142 "Refolding of Recombinant Proteins", Tadahiko Kohno et. al., Methods in Enzymology, Vol 185, pp 187-195, 1990 "E. coli expression and characterization of a mutant troponin I with the three cysteine residues substituted", Lan Kluwe et. al., FEBS, Vol 323, number 1.2, pp 83-88, May 1993 Date: Examiner:

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ATTY DOCKET NO. SERIAL NO. **FORM PTO-1449** 10/080,919 INFORMATION DISCLOSURE STATEMENT 22918/1 APPLICANT(S): Lucia Irene Gonzalez-Villasenor FILING DATE: ART UNIT: February 22, 2002 UNITED STATES PATENT DOCUMENTS SUB FIL. EXAM. **DOCUMENT** DATE IF CLASS INITIAL NUMBER DATE INVENTOR CLASS APPR FOREIGN PATENT DOCUMENTS **CLASS** SUB TRAN DATE COUNTRY **DOCUMENT NUMBER** CLASS Y/N OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) "Expression and equilibrium denaturation of cardiac troponin I: stabilization of a folding intermediate during denaturation by urea", Nihmat Morjana et al., Biotechnol. Appl. Biochem. (1998), 28, pp 7-17 11 "The Cyanogen Bromide Reaction", Erhard Gross, Cleavage of Peptide Chains, pp 238-263 2 Z "Gel Electrophoresis and Isoelectric Focusing of Proteins - Selected Techniques", R.C. Allen et. al., 1984 "In vitro folding of inclusion body proteins", Rainer Rudolph et. al., The FASEB Journal, January 1996, Vol 10, pp 49-24 "Purification and Immunogenicty of Fusion VP1 Protein of Foot and Mount Disease Virus", Steven J. Shire et. al., Biochemistry, 1984, 23, 6474-6480 "Examination of calf prochymosin accumulation in Escherichia coli: disulphide linkages are a structural component of 16 prochymosin-containing inclusion bodies", J.M. Schoemaker et. al., The EMBO Journal, 1985, Vol. 4, No. 3, pp 775-780 "Recovery of soluble human renin from inclusion bodies produced in recombinant Escherichia coli", Satish K. Sharma, . 7 Journal of Biotechnology, 4 (1986) 119-124 "Isolation and purification of protein granules from Escherichia coli cells overproducing bovine growth hormone", Ronald G. Schoner et. al., Bio Technology, February 1985, pp 151-154 24 "Size and density of protein inclusion bodies", G. Taylor et. al., Bio/Technology, Vol 4, June 1986, pp 553-557 "Alteration of catalytic properties of chymosin by site-directed mutagenesis", Junko Suzuki et. al., Protein Engineering. Vol. 2, No. 7, pp 563-569, 1989 "Site-directed mutagenesis reveals functional contribution of Thr218, Lys220 and Asp304 in chymosin", Junko Suzuki et. al., Protein Engineering, Vol. 4, No. 1, pp 69-71, 1990 Examiner: Date:

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ATTY DOCKET NO. SERIAL NO. **FORM PTO-1449** INFORMATION DISCLOSURE STATEMENT 10/080,919 22918/1 APPLICANT(S): Lucia Irene Gonzalez-Villasenor FILING DATE: ART UNIT: February 22, 2002 UNITED STATES PATENT DOCUMENTS SUB FIL. DOCUMENT EXAM. CLASS **DATE IF** CLASS INITIAL NUMBER DATE INVENTOR APPR FOREIGN PATENT DOCUMENTS SUB TRAN DOCUMENT NUMBER DATE COUNTRY CLASS CLASS Y/N OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) "Troponin I is present in human cartilage and inhibits angiogenesis", Marsha A. Moses et. al., Proc. Natl. Acad. Sci. USA, Vol. 96, pp 2645-2650, March 1999 "Structure, evolution, and regulation of a fast skeletal muscle troponin I gene", Albert S. Baldwin et. al., Proc. Natl. Acad. Sci. USA, Vol. 82, pp 8080-8084, December 1985 "Utilization of Zeolite Y in the removal of anionic, cationic and nonionic detergents during purification of proteins", Zoltan Blum et. al., Biotechnology Techniques, Vol 5, No. 1, pp 49-54, (1991) "Principles that govern the folding of Protein Chains", Christian B. Anfinsen, SCIENCE, 20 July 1973, Volume 181, Number 4096, pp 223-230 "Overexpression of human cardiac troponin-I and troponin-C in Escherichia coli and their purification and characterization - Two point mutations allow high-level expression of troponin-I", Eman AL-HILLAWI et. al., Eur. J. 45 Biochem., 225, pp 1195-1201, (1994) "Recombinant protein expression in Escherichia coli", François Baneyx, Current Opinion in Biotechnology, 1999, Vol. 10, pp 411-421 "Structure and morphology of protein inclusion bodies in Escherichia coli", Gregory A. Bowden, Bio/Technology, Vol 9, August 1991, pp 725-730 "Renaturation, purification and characterization of recombinant F_{ab}-fragments produced in Escherichia coil". Johannes Buchner et. al., Bio/Technology, Vol. 9, February 1991, pp 157-162 49 "Stabilization of Protein Structure by Sugars", Tsutomu Arakawa et. al., Biochemistry, 1982, Vol. 21, pp 6536-6544 "Synthesis and cloning of a gene coding for a fusion protein containing mouse epidermal growth factor", G. Allen et.al., Journal of Biotechnology, Vol. 5, (1987) pp 93-114 51 "Denatured States of Proteins", Ken A. Dill, Annu. Rev. Biochem., 1991, Vol. 60, pp 795-825 Date: Examiner:

Sheet 6 of 10

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	5)	"Choice of Cellular Protein Expression System", David Gray et. al., <u>Current Protocols in Protein Science</u> , (2000), pp 5.16.1-5.16.34							
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	58	"Nativelike Secondary Structure in Interleukin-1ß Inclusion Bodies by Attenuated Total Reflectance FTIR", Keith Oberg et. al., Biochemistry, 1994, Vol. 33, pp 2628-2634							
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	€1	"Solubility as a function of protein structure and solvent components", Catherine H. Schein, Bio/Technology, Vol. 8, April 1990, pp 308-317							
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DOCKET NO. SERIAL NO. **FORM PTO-1449** 10/080,919 INFORMATION DISCLOSURE STATEMENT 22918/1 APPLICANT(S): Lucia Irene Gonzalez-Villasenor ART UNIT: FILING DATE: February 22, 2002 UNITED STATES PATENT DOCUMENTS SUB FIL. EXAM. DOCUMENT DATE IF CLASS DATE **INVENTOR CLASS** INITIAL NUMBER APPR FOREIGN PATENT DOCUMENTS **CLASS** SUB TRAN **COUNTRY** DOCUMENT NUMBER DATE **CLASS** Y/N OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) "Synthesis of calf prochymosin (prorennin) in Escherichia coli", J.S. Emtage, Proc. Natl. Acad. Sci. USA, Vol. 80, pp 3671-3675, June 1983 "High-Level Expression in Escherichia coli of Biologically Active Bovine Growth Hormone", Henry J. George et. al., DNA, Volume 4, Number 4, 1985, pp 273-281 "Purification of Recombinant Proteins", Paul T. Wingfield, Current Protocols in Protein Science, 1997, 6.0.1.-6.7.10 64 "Reconstitution of Lactic Dehydrogenase. Noncovalent Aggregation vs. Reactivation. 2. Reactivation of Irreversibly Denatured Aggregates", Rainer Rudolph et. al., Biochemistry, Vol 18, No. 25, 1979, pp 5572-5575 "Gene Expression in Recombinant Escherichia coli", Joan Stader, 1995, pp 1-51 "Gene Expression in Recombinant Bacillus", Matti Sarvas, Gene Expression in Recombinant Mocroorganisms, 1995, pp Ė7 55-120 "Use of Stabilizing Additives". Ciaran O'Fagain, Stabilizing Protein Function, 1997, pp 69-79 "Recombinant human insulin-like growth factor II expressed in Escherichia coli", Thomas C. Furman et. al., 69 Bio/Technology, Vol. 5, October 1987, pp 1047-1051 "High-Level Expression and Purification of the Recombinant Diphtheria Fusion Toxin DTGM for PHASE I Clinical Trials", Arthur E. Frankel et. al., Protein Expression and Purification, 16, 190-201, (1999) Date: Examiner:

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TY DOCKET NO. SERIAL NO. **FORM PTO-1449** INFORMATION DISCLOSURE STATEMENT 10/080,919 22918/1 APPLICANT(S): Lucia Irene Gonzalez-Villasenor FILING DATE: ART UNIT: February 22, 2002 UNITED STATES PATENT DOCUMENTS SUB FIL. EXAM. DOCUMENT **CLASS** DATE IF INITIAL DATE CLASS NUMBER INVENTOR APPR FOREIGN PATENT DOCUMENTS SUB TRAN **CLASS** DOCUMENT NUMBER DATE COUNTRY **CLASS** Y/N OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) "Recovery of soluble, biologically active recombinant proteins from total bacterial lysates using ion exchange resin". Adolf Hoess et. al., Bio/Technology, Vol. 6, October 1998, pp 1214-1217 "Renaturation of Recombinant Proteins Produced as Inclusion Bodies", Bernhard E. Fischer, Biotech. Adv., Vol. 12, pp. フィ 89-101, 1994 "Refolding and crystallographic studies of eukaryotic proteins produced in Escherichia coli", Kiyoshi Nagai et. al., Biochemical Society Transactions, 1988, Vol. 16, pp 108-110 "Protein folding intermediates and inclusion body formation", Anna Mitraki et. al., Bio/Technology, Vol. 7, July 1989, 14 pp 690-697 "Overview of Protein Expression in Saccharomyces cerevisiae", Robert L. Strausberg, Production of Recombinant 75 Proteins, 1995, pp 5.6.1-5.6.7 "Production of recombinant proteins", Paul T. Wingfield, Current Protocols in Protein Science, Supplement 20, 2000, pp 76 5.0.1-5.16.25 "Fermentation and Growth of Escherichia coli for Optimal Protein Production", Alain Bernard et. al., Current Protocols in Protein Science, 1995, pp 5.3.1-5.3.18 "Protein Folding and its Implications for the Production of Recombinant Proteins", Roman Hlodan et. al., Biotechnology 7,5 and Genetic Engineering Reviews, Vol. 9, December 1991, pp 47-88 "Reconstitution of Rabbit Skeletal Muscle Troponin from the Recombinant Subunits All Exressed in and Purified from E. coli, Setsuko Fujita-Becker et. al., J. Biochem., 114, 438-444, (1993) "A novel sequential procedure to enhance the renaturation of recombinant protein from Escherichia coli inclusion bodies", Bernhard Fischer et. al., Protein Engineering, Vol. 5, No. 6, pp 593-596, 1992 Examiner: Date:

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FORM PTO-1449

SERIAL NO.

INFORMATION DISCLOSURE STATEMENT 10/080,919 22918/1 APPLICANT(S): Lucia Irene Gonzalez-Villasenor FILING DATE: ART UNIT: February 22, 2002 UNITED STATES PATENT DOCUMENTS **SUB** FIL. DOCUMENT EXAM. DATE IF **CLASS** NUMBER DATE **INVENTOR CLASS** INITIAL APPR FOREIGN PATENT DOCUMENTS **CLASS SUB** TRAN **DOCUMENT NUMBER** DATE COUNTRY CLASS Y/N OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) "Optimized procedures for purification and solubilization of basic fibroblast growth factor inclusion bodies", D. Estape et. al., Biotechnology Techniques, Vol. 10, No. 7, July 1996, p 481-484 "The Use of Zeolite Y in the Purification of Intra Cellular Accumulated Proteins from Genetically Engineered Cells, Hakan Eriksson et. al., Biotechnology Techniques, 1992, pp 239-244 "Convenient and Efficient In Vitro Folding of Disulfide-Containing Globular Protein from Crude Bacterial Inclusion 03 Bodies", Junichiro Futami et. al., J. Biochem., Vol. 127, pp 435-444 (2000) "Enzyme Applications", M.D. Trevan et. al., Biotechnology: The Biological Principles, 1987, pp 203-210 'Comparing the Refolding and Reoxidation of Recombinant Porcine Growth Hormone from a Urea Denatured State and 35 from Escheria coli Inclusion Bodies", Michael Cardamone et. al., Biochemistry 1995, Vol. 34, pp 5773-5794 "The use of EDTA or Polymyxin with Lysonzyme for the Recovery of Intracellular Products from Escherichia coli", C.R. Dean et. al., Biotechnology Techniques, Volume 6, No. 2 March/April 1992 pp 133-138 "Serodiagnosis of Antibodies to the Human AIDS Retrovirus with a Bacterially Synthesized ENV Polypeptide", Cirilo D. 87 x Cabradilla, Bio/Technology, Vol. 4, February 1986, pp 128-133 "Aggregation and Denaturation of Apomyoglobin in Aqueous Urea Solutions", Linda R. De Young et. al., Biochemistry, 23 1993, 32, 3877-3886 19 "Refolding of recombinant proteins", Eliana De Bernadez Clark, Biochemical Engineering, 1998, 9, 157-163 "Pharmacoeconomics", Joseph F. Heyse et. al., Encyclopedia of Biopharmceutical Statistics, 2000, pp 387-401 "Recombinant DNA Proteins and Drug Discovery", Christopher Hentschel, Genetically Engineered Human Therapeutic Drugs, 1988, pp 3-6 "Chapter 8. Bioproducts and Economics", Harvey W. Blanch et. al., Biochemical Engineering, 1996, pp 609-671 Date: Examiner:

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